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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ILLUMINA, INC., and
ILLUMINA CAMBRIDGE LTD.,

Plaintiffs,

v.

BGI GENOMICS CO., LTD.,
BGI AMERICAS CORP.,
MGI TECH CO., LTD.,
MGI AMERICAS, INC., and
COMPLETE GENOMICS INC.,

Defendants.

COMPLETE GENOMICS INC.,

Counterclaim-Plaintiff,

v.

ILLUMINA, INC., and
ILLUMINA CAMBRIDGE LTD.,

Counterclaim-Defendants

Case No. 3:19-cv-03770-WHO

NOTICE OF MOTION AND MEMORANDUM IN SUPPORT OF PLAINTIFFS ILLUMINA, INC. AND ILLUMINA CAMBRIDGE LTD.'S MOTION FOR PRELIMINARY INJUNCTION

Date: March 25, 2020
Time: 2:00 p.m.
Courtroom: 2, 17th Floor

Hon. William H. Orrick

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I. NOTICE OF MOTION

Pursuant to Federal Rule of Civil Procedure 65 and Civil L.R. 7, plaintiffs Illumina, Inc. and Illumina Cambridge, Ltd. (collectively "Illumina") move for a preliminary injunction prohibiting BGI Americas Corp. ("BGI Americas"), MGI Tech Co., Ltd. ("MGI Tech"), MGI Americas, Inc. ("MGI"), and Complete Genomics, Inc. ("Complete Genomics")[1] from distributing their infringing sequencers and sequencing reagents in the United States based on U.S. Patent Nos. 7,566,537 ("the '537 Patent") and 9,410,200 ("the '200 Patent") or using those products in the United States to promote them to third parties. This motion is based on this submission, the Declarations of Mark Van Oene, Professor Kevin Burgess, and Doug McClellan, and all other information properly considered. The hearing is noticed for March 25, 2020 at 2:00 pm in Courtroom 2.

II. RELIEF SOUGHT

Illumina requests the entry of a preliminary injunction prohibiting Defendants from distributing their infringing sequencers and sequencing reagents in the United States or using those products in the United States to promote them to third parties.

III. INTRODUCTION

Defendants have been selling their imitative sequencing products, such as their G400RS sequencer, head-to-head against Illumina using Illumina's patented [redacted]. To date, the distribution of Defendants' sequencers to customers has been focused on China where IP counterparts to the '537 and '200 Patents do not exist. To date, Defendants have not attempted general commercialization in the United States because of Illumina's patent rights.

Over the last few weeks Defendants have informed Illumina that they have a plan to try to distribute their infringing sequencing products to "key opinion leaders" ("KOLs") in the United States. They plan to offer the infringing [redacted] products on a "no-cost trial basis" to these potential customers. Defendants state that such shipments may start in late March if they follow through, although they are not certain that such placements will happen.

[1] Collectively, they are referred to as "Defendants" or "BGI".

Defendants' free "trial offer" of its infringing G400RS sequencers (featuring Illumina's patented [redacted]) to key opinion leaders is designed to inflict irreparable harm. A free trial offer is a classic marketing tool to penetrate desirable customers. Defendants' explicit targeting of key opinion leaders is obviously intended to amplify this marketing effort to persuade purchasers broadly that Defendants' cheaper imitation sequencers, using Illumina's patented [redacted], work well enough to be seriously considered compared to Illumina's state-of-the-art patented sequencers.

As explained further by Illumina's Chief Commercial Officer Mark Van Oene in his supporting declaration, Defendants' "trial offer" marketing initiative is likely to cause substantial irreparable harm for a host of reasons. First, it is common to start a commercial release with key opinion leader placements because they are typically big customers and influence the broader market. This no-cost trial offer program for key opinion leaders is an effective way to "chum" the waters to create pent up demand in a market for a broader roll out. Second, since many of the most influential opinion leaders are in the United States, Defendants can use validation of their infringing sequencers via domestic infringement to boost worldwide sales improperly. Third, the market can use these key opinion leader validations of its cheaper sequencers distributed on a no-cost trial basis as a cudgel to demand price reductions from Illumina with the specter of a broader release. Fourth, Defendants also appear to be using this initiative to penetrate key opinion leaders with its established products to promote their attempt at an alleged "design around" which they plan to broadly promote commercially in the United States this Spring. It is improper for Defendants to use their infringing technology to promote other products. This too creates a serious risk of irreparable harm.

Defendants' responses are unavailing. Although Defendants are now actively approaching key opinion leaders in the United States with their no-cost trial offer for their infringing sequencers, they only expect five or less key opinion leaders to accept that offer in the near term, and thus their program is allegedly de minimis. Defendants argue that this is such incidental conduct that they should not be stopped. This argument fails because the harm caused by key opinion leader infringement is magnified precisely because they are key opinion leaders. Moreover, if this activity

were truly de minimis, Defendants would not be incurring the legal problems attendant to this conscious expansion of its United States infringement.

Defendants also contend that this activity is supposedly non-commercial research work. This argument fails resoundingly because the infringing products -- including the G400 sequencer that Defendants are trying to give away on a trial basis -- have been on sale for years outside the United States. Indeed, Defendants have placed over 1,000 sequencers outside the United States that use Illumina's patented technology. And if there were a need for research on this mature product, there is no reason that could not be done in China where they have their headquarters and hundreds of sequencers are commercially deployed.

Defendants cannot credibly contest Illumina's likelihood of success. Defendants' infringement is straightforward, and their desire to expand it to key opinion leaders is unwarranted. In their discovery response, Defendants failed to identify a non-infringement argument. The record here is even more compelling than the record before Judge Alsup when he enjoined the last multi-national that sought to use Illumina's patented azido chemistry for sequencers in the United States. *See Illumina, Inc. v. Qiagen, NV*, 207 F. Supp. 3d 1081 (N.D. Cal. 2016). Those patents rights are even more battle hardened and proven now that BGI's IPR invalidity attacks have failed, too. A preliminary injunction should be entered.

IV. FACTUAL BACKGROUND

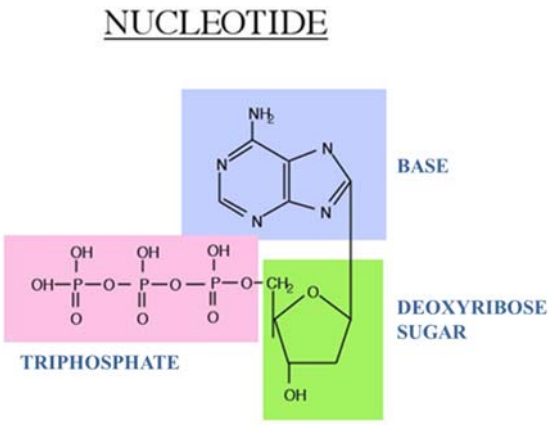
A. Overview Of Sequencing-by-Synthesis

Illumina's patented innovations have revolutionized the genetics field and established its proprietary SBS technology as the premier DNA sequencing method in terms of efficiency, accuracy, and reliability. *See* Van Oene Decl. ¶¶ 8, 10-12. Illumina is a recognized industry leader in DNA sequencing, and its technology is used to generate over 90% of the world's sequencing data. *Id.* at ¶¶ 12, 34.

The SBS technique is summarized in the accompanying declaration of Professor Kevin Burgess. *See* Burgess Decl ¶¶ 30-37. The key aspects of SBS are as follows.

DNA is a molecule made up of four chemical bases: adenine, guanine, cytosine, and thymine. Each of the bases in DNA is also attached to a sugar molecule and a phosphate molecule.

Id. ¶ 31. The combination of the base, sugar, and phosphate molecule is called a nucleotide. A representative nucleotide is shown below, with each of its components highlighted:



The four nucleotides that make up DNA are labeled according to the base they contain: "A" for adenine, "G" for guanine, "C" for cytosine, and "T" for thymine. DNA consists of two paired strands of nucleotides that wind around one another to form a double helix. In forming the double helix, the nucleotides of one strand pair up with nucleotides of another strand in a specific way: G only pairs with C, and A only pairs with T. *Id.*

In SBS, the DNA strand of interest (the "target strand") is sequenced by sequentially incorporating nucleotides into a "complementary" DNA strand. The target DNA strand consists of just one half of the DNA double helix (i.e., a single strand of DNA) and the complementary strand, once synthesized, comprises the second strand of the DNA double helix. *Id.* ¶ 32. Each of the four different kinds of nucleotides used in SBS can include a chemical "label" that can be read in order to distinguish the different nucleotides. After a nucleotide is incorporated into the complementary strand, the nucleotide is read. Then, the next nucleotide is incorporated into the complementary strand, and the nucleotide is again read. By repeatedly incorporating nucleotides and reading the nucleotide, the DNA sequence can be determined. *Id.*

The different components that are involved in this process in SBS as carried out in the Illumina sequencing platform may be illustrated in the figure below:

As an initial step, the target DNA strand (shown as a purple/green strand) is attached to a surface. By attaching the target strand to a surface, the target strand will stay at a fixed position throughout the sequencing process, which enables one to image the target strand throughout the steps of the SBS process. *Id.* ¶ 33. Next, a "sequencing primer" (shown in blue) is matched up to the target strand. The primer matches up to the target strand through a hybridization process whereby the individual nucleotides of the primer pair up with complementary nucleotides (shown in purple) in the target strand. *Id.*

The next step is to add a single nucleotide to the primer thereby synthesizing the complementary strand. Typically, this is done using an enzyme that can catalyze the incorporation of a nucleotide into a DNA molecule. *Id.* ¶ 34. One example of such an enzyme is the DNA polymerase enzyme. *Id.* The enzyme requires the presence of the primer to add a nucleotide, which is why the primer is used. The nucleotide that gets added to the complementary strand depends on the sequence of the next base in the target strand. If the next nucleotide in the target strand is A, then a T will be added to the primer; if the next nucleotide is T, then A will be added; if the next nucleotide is G, then C will be added; if the next nucleotide is C, then G will be added. In the illustration below, the first nucleotide in the target strand is an A, so a T was added to the blue primer. *Id.* ¶ 34. The T that is added is shown in light blue:

Each of these added bases is blocked in a way that only permits one base to be added at a time. *Id.* ¶ 33. In the figure above, the "block" is depicted by a square on the bottom of the T that was added. This "block" is also referred to as a "protecting group." Illumina's system repeats this process of adding a nucleotide, reading the detectable label, and removing the block for multiple rounds. In this way, Illumina's system reveals a sequence of nucleotides by monitoring the identity of each nucleotide incorporated into the complementary strand.

Illumina's system is massively parallel in that it sequences and records readings of multiple complementary strands during each round of SBS. *Id.* ¶ 37. Each complementary strand is located in a different area on the sequencing flow cell's surface. *Id.* Thus, the sequence of nucleotides at each complementary strand can be deduced by looking at the reads at each spot in each round of SBS (each spot corresponding to a different DNA strand). *Id.*

B. The '537 Patent

The '537 Patent, entitled "Labelled Nucleotides," issued on July 28, 2009. Claims 1-6 and 8 of the '537 Patent cover the portion of the SBS method whereby labelled nucleotides are incorporated into a complementary DNA strand. Claim 1, the sole independent claim of the '537 Patent states:

> 1. A method of labeling a nucleic acid molecule, the method comprising incorporating into the nucleic acid molecule a nucleotide or nucleoside molecule, wherein the nucleotide or nucleoside molecule has a base that is linked to a detectable label via a cleavable linker and the nucleotide or nucleoside molecule has a ribose or deoxyribose sugar moiety, wherein the ribose or deoxyribose sugar moiety comprises a protecting group attached via the 2′ or 3′ oxygen atom, and said protecting group can be modified or removed to expose a 3′ OH group and the protecting group comprises an azido group.

As set forth in the claim, the nucleotide includes the following features: (1) a base linked to a detectable label via a linker that can be cleaved, and (2) a protecting group on the 2'or 3' sugar of the nucleotide that comprises an azido group. By attaching the label to the nucleotide via a "linker" that can be cleaved, one can remove the label from the nucleotide after the nucleotide has been added to the complementary strand. By doing so, the optical properties of the label will not interfere with or obscure the signal that can be detected from the label on the ***next*** nucleotide that is added. *Id.* ¶ 40. Similarly, as the '537 Patent explains, the "protecting group is intended to prevent nucleotide incorporation onto a nascent polynucleotide strand, and can be removed under defined conditions to allow polymerisation to occur." Burgess Decl, Ex. B at 7:51-53. In other words, by having a "protecting group" in the nucleotide, the nucleotide will be added to the complementary strand, and no additional nucleotides will be added. *See* Burgess Decl. ¶ 42. The individual nucleotide can then be imaged without interference from another labeled nucleotide.

The "azido" protecting group recited in the claims has the additional property that when it is removed a 3′ OH chemical group on the sugar is exposed. *Id* ¶ 43. This is important. An OH group at the 3′ position of the sugar is the natural state of the sugar as found in natural nucleotides. Only when the sugar is in this state with an OH group at the 3′ position can another nucleotide be added to the complementary strand. By requiring "protecting groups" that "can be modified or removed to expose a 3′ OH group," the claims thus allow one to control when a nucleotide is added to the complementary strand. *Id.*

The '537 Patent, accordingly, describes techniques for incorporating labeled nucleotides into DNA molecules in the efficient and controllable manner that is required for large-scale SBS with an effective protecting group. Illumina's patented contributions ultimately helped to make this large-scale technique practical.

C. The '200 Patent

The '200 Patent, entitled "Labelled Nucleotides," issued on August 9, 2016 and is closely related to the '537 Patent. Claim 1, the sole independent claim of the '200 Patent states:

1. A method of labeling a nucleic acid molecule, the method comprising:

incorporating into the nucleic acid molecule a nucleotide molecule using a

> polymerase, wherein the nucleotide molecule has a base that is linked to a fluorophore via a cleavable linker and the nucleotide molecule has a deoxyribose sugar moiety,
>
> wherein the deoxyribose sugar moiety comprises a protecting group attached via the 3′ oxygen atom, and said protecting group can be modified or removed to expose a 3′ OH group, the protecting group comprising an azido group.

Claim 1 of the '200 Patent is slightly narrower than claim 1 of the '537 Patent, which has been upheld after failed validity challenges in multiple IPR proceedings. *See* Burgess Decl. ¶ 28.

D. Defendants Have Been Selling Their Imitative Sequencers Using Illumina's Patented [redacted] Outside The United States To Directly Compete Against Illumina's Sequencers

In 2017, the President of BGI Genomics stated publicly that the company plans to "dominate the market" in genomics. Van Oene Decl. ¶ 45, Van Oene Decl., Ex. BB at 1. Last year, Defendants announced that they had already placed over 1,000 sequencers in 16 different countries and had a 35% market share in China. *Id.*

Defendants' "G400" is a production scale sequencer. *Id.* ¶ 21. Defendants launched it as the MGISEQ-2000 back in October 2017 and now call it the DNBSEQ-G400. *Id.* ¶ 54.

Many people in the industry have recognized Defendants' sequencers as imitative of Illumina sequencing products. *Id.* ¶ 33. For example, based on interviews with MGI, GenomeWeb reported that MGI was using SBS "chemistry [] similar to that used by Illumina and others." *Id.* ¶ 33, Van Oene Decl., Ex. L at 4. As mentioned above, MGI itself has touted its own use of the "[p]roven sequencing by synthesis (SBS) chemistry" to potential customers to compete against Illumina. Van Oene Decl., Ex. O at 4, No. 3. When MGI entered the European market, it marketed its sequencers using the designation "MGISEQ," which is nearly identical to Illumina's registered European Union trade mark "MISEQ" for its sequencing systems and reagents. An industry commentator observed the remarkable similarity between the appearance and model names of Illumina's instruments and a BGI copy product, stating that Defendants' product "not only looks like an Illumina (NASDAQ:ILMN) sequencer but they're actually using the same naming convention as the Illumina machines." Van Oene Decl., Ex. P at 1 ("The BGI Genomics IPO – Is This a Chinese Illumina?"). MGI changed the name of its sequencing platforms after Illumina

obtained a preliminary injunction in Latvia, the planned location for MGI's European distribution center, to prevent MGI's continued trademark infringement. Van Oene Decl. ¶ 33.

MGI attempts to position its imitative products as comparable to Illumina's sequencers in performance, while undercutting Illumina on price. Van Oene Decl., Ex. O at 3 ("a significant reduction in costs compared to Illumina instruments."); Van Oene Decl., Ex. L at 3 ("Tan said MGI's platforms will be very cost-competitive with Illumina's."). In a press release of May 21, 2019, MGI claimed that "analyses have shown that MGI's data quality is comparable to data generated using a competitor's [i.e., Illumina's] technology, but that sequencing costs are lower." Van Oene Decl., Ex. R at 1. Industry analysts have also reported that MGI "compete[s] with Illumina on cost" and "may apply pressure to Illumina's margins." Van Oene Decl., Ex. D at 36, 84.

The direct competition between Illumina and MGI is also evident in MGI's marketing materials, which often use Illumina's sequencers as a benchmark, typically to make cost comparisons and performance comparisons based on comparative testing. Van Oene Decl. ¶ 35. Below is an image from a presentation given in Warsaw by an MGI Field Application Scientist that illustrates how MGI targets a spectrum of Illumina sequencers (from the MiniSeq to the NovaSeq platforms) in its marketing efforts.

Id.

In this same presentation, MGI provided an "NGS Running Cost Comparison" to support its claim that it provides equivalent NGS performance to Illumina, but at a lower price. *Id.* at 121. MGI's slides show a list price cost per GB of sequencing from $10-$143 for Illumina, as compared to $5-$32 for MGI. *Id.* For the highest-production sequencers, MGI shows up to a 75% discount for its DNBSEQ-T7 ($5 per GB) as compared to Illumina's NovSeq ($10-20 per GB). *Id.* In addition, the typical cost of reagents for sequencing a human genome using Illumina's NovaSeq 6000 platform is approximately $800. By comparison, in the above-mentioned GenomeWeb article, MGI advertises its equivalent DNBSEQ-T7 instrument as costing approximately $500 in consumables per human genome. Van Oene Decl., Ex. L at 3.

In "The Sequencing Buyer's Guide" (which is sponsored by MGI, among others), David Smith of the Mayo Clinic identifies "BGI-based sequencing" as a lower-cost substitute for Illumina's technology. He states, "[o]ne of the most attractive aspects of BGI-based sequencing is that they offer a price-point for WGS [whole genome sequencing] that is really hard to beat of $600. This is an all-in cost of library preparation, sequencing and post-sequencing analysis. As will be discussed later in this report, this is considerably less than the full cost of WGS on the only other viable platform for WGS, namely Illumina." Van Oene Decl, Ex. JJ at 14. Mr. Smith also notes in The Sequencing Buyer's Guide that BGI's sequencers (such as the BGISEQ-500) "were mainly sold in China (most likely due to patent issues on the actual sequencing chemistry)" and further mentions that "there were a number of patent violation lawsuits filed between Illumina and MGI." *Id.* at 13-14.

MGI targets Illumina's existing customers and attempts to use existing Illumina infrastructure to induce Illumina's customers to replace their Illumina sequencers with MGI products, touting MGI's "[c]ompatibility with previous Illumina platforms." Van Oene Decl., Ex. O at 4. For example, MGI markets its DNBSEQ instruments as being "fully compatible with lab infrastructure that has been set up with Illumina's instrumentation," stating that they generate files that are "compatible with bioinformatics workflows written for sequencing data from Illumina instruments" and that "[l]ibraries already constructed with Illumina-style adapters can be converted easily to [MGI's] platform." *Id.* at 4-5. MGI also offers data analysis software to accompany the

actual sequencing instrument that is similar to Illumina's offering. Illumina offers a variety of bioinformatics software to run with its sequencers. For example, the MiSeq runs through BaseSpace Sequence Hub, Illumina's cloud-based interface, the analytical software tool MiSeq Reporter Software. Van Oene Decl., Ex. X (Illumina MiSeq System web page). MGI has also marketed its products as being fully compatible with Illumina's platforms and related lab infrastructure, including Illumina's libraries and bioinformatics workflows. Van Oene Decl, Ex. O at 4-5.

E. Defendants Infringe Illumina's Patents

[redacted] McClellan Decl, Ex. 1 at 6. [redacted] McClellan, Decl., Exs. 3-7.

Each of the Defendants should be preliminarily enjoined because they are collaborating together to commit infringements and for potential commercialization in the U.S. First, the Defendants have provided notice that MGI Americas, Inc. ("MGI") intends to supply accused BGI sequencers and accused reagents to key opinion leaders in the U.S. on a no-cost basis. Van Oene Decl., Ex. FF; Ex. McClellan Decl., Ex. 8. [redacted]

[redacted]

F. Defendants Reveal Their Program For No-Cost Trial Offers To Key Opinion Leaders In The United States

On January 28, 2020, Defendants notified Illumina that "MGI America may begin placing sequencers with key opinion leaders on a ***no-cost trial basis*** and may provide sequencing reagent kits to key opinion leaders on a no-cost basis (for their use with the sequencers or for sequencing performed by MGI Americas), where such kits may include, but are not limited to, those with the labeled nucleotides that are presently accused." Van Oene Decl., Ex. FF at p. 14 (emphasis supplied). Defendants also notified Illumina that MGI plans to commercially release an unidentified design-around attempt. *Id*. at pp. 10-14.

On February 4, 2020, Defendants revealed that their engagement with key opinion leaders in the United States is "on-going" and that they are attempting to place their G400 sequencers (which have been on the market outside the United States for years) with key opinion leaders. *Id*. at pp. 6-8. Defendants explained that they thought that "realistically" they would not place the infringing reagent kits until the end of March at the earliest. *Id.*

On February 12, 2020, Defendants stated that they planned to give away the infringing reagents kits as well as their G400 sequencers on a trial basis, but then oddly stated that they did not have a plan to do so right now. *Id.*at 2. However, Defendants expressly stated that they reserve the right to do this when they want -- without notice to Illumina. *Id.*

In response, Illumina's counsel requested that Defendants agree not to distribute the accused sequencing kits in the United States to key opinion leaders to avoid the need for this preliminary injunction motion. *Id.* at 1-2. On February 14, 2020, [redacted]

[redacted] McClellan Decl., Ex. 8 at 1.

Because Defendants' key opinion leader program is infringing and is likely to cause irreparable harm to Defendants, Illumina brings this motion. Importantly, Defendants did not agree that this would be the end of its commercialization effort – rather it is clear that it is the beginning.

V. ARGUMENT

"The factors the trial court considers when determining whether to grant a preliminary injunction are of longstanding and universal applicability. As the Supreme Court recently reiterated, there are four: "[a] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375–76 (Fed. Cir. 2009). All these factors weigh strongly in favor of preliminarily enjoining Defendants from infringing the '537 and '200 Patents through its proposed key opinion leader program or other transfer to third parties.

A. Illumina Is Likely To Succeed On The Merits

A reasonable likelihood of success requires a showing of infringement and that the asserted patent will withstand a validity challenge. *See, e.g.*, *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994).

1. Defendants' Accused Reagent Kits Infringe When Used On Their G400 And Other Sequencers In Their Facility And At Key Opinion Leaders

Infringement is present when an accused product or process contains every limitation in the asserted claims. *Uniloc USA, Inc. v. Microsoft Corp.* 632 F.3d 1292, 1301 (Fed. Cir. 2011). "Determining literal infringement is a two-step process: the 'proper construction of the asserted claim and a determination whether the claim as properly construed reads on the accused product or method.'" *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012) (quoting *Georgia–Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1330 (Fed. Cir. 1999)).

Professor Burgess in his report establishes that the accused products use Illumina's patented [redacted] and infringe Illumina's '537 and '200 Patents. Burgess Decl. ¶¶ 49-79. He explains that every claim element is satisfied when these products are used for their intended purpose. *Id*. Moreover, by encouraging their products use by key opinion leaders with knowledge that they infringe, Defendants induce infringement. *Global-Tech Appliances, Inc. v. SEB SA*, 563 U.S. 754 (2011). By supplying accused reagent kits that have no substantial non-infringing uses, Defendants also contributorily infringe. *Id.*

In their discovery response in this case regarding their position on infringement, Defendants did not deny that the use of their accused reagent kits use are covered by Illumina's '537 and '200 Patents. McClellan Decl., Ex. 2 at 6-7. Instead, Defendants refer to alleged invalidity and unenforceability and the supposed lack of use of these kits in the United States. *Id.* They do not contend that any claim elements are unmet. *Id.* Illumina is likely to succeed on its infringement claims.

2. Defendants' Invalidity Position Is Insubstantial

Another multi-national, Qiagen N.V., attempted to introduce sequencers using Illumina's patented azido chemistry in 2016. *See Illumina, Inc. v. Qiagen, NV*, 207 F. Supp. 3d 1081, 1084-1085 (N.D. Cal. 2016). Before doing so, it attempted to challenge the '537 patent-in-suit before the PTAB. The PTAB upheld Illumina's patent after a trial. *Id.* Qiagen appealed to the Federal Circuit, which also upheld Illumina's patent. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd*., 821 F.3d 1359 (Fed. Cir. 2016).

Although its validity challenges failed before the PTAB, Qiagen attempted to nevertheless introduce its infringing sequencers into the United States. In doing so, it attempted to argue that there were still substantial questions as to the validity of Illumina's '537 patent. Judge Alsup thoroughly rejected that argument and found that it is likely the validity of Illumina's patent rights will be upheld. *Illumina*, 207 F. Supp. 3d at 1087-93. Because of the strength of Illumina's azido patent rights, Judge Alsup found that Illumina presented a "powerful" case for an injunction. *Id.*

Because Defendants are so eager to introduce their imitative sequencers in the United States, and are so aware of Illumina's patent rights, in 2017 they invested in two IPRs trying to challenge

the '537 Patent even though Qiagen's IPR had already failed. *See Complete Genomics, Inc. et al v. Illumina Cambridge Ltd. et al, IPR2017-02172 (PTAB), Decision Denying Institution (April 20, 2018); Complete Genomics, Inc. et al v. Illumina Cambridge Ltd. et al, IPR2017-02174 (PTAB), Decision Denying Institution (April 20, 2018).* The PTAB rejected Defendants' challenges because one was duplicative of Qiagen's prior failed IPR and their second IPR failed to show a reasonable likelihood on the merits that the '537 Patent was invalid. *Id.*

In a strained attempt to undermine Judge Alsup's analysis, the PTAB's three decisions and the Federal Circuit's decision, Defendants pled a meritless inequitable conduct argument that dubiously argued that all those decisions were the product of fraud. This Court rejected Defendants' attempt to even plead this inequitable conduct argument because Defendants' theory was implausible. Dkt. 81 at 8-9.

Illumina's patent rights are valid and battle-tested. Illumina is likely to win an invalidity challenge.

B. There Is A Substantial Risk That Illumina Would Suffer Irreparable Harm If Defendants Are Permitted To Pursue Its Plan To Distribute Its Infringing Products To Key Opinion Leaders On A No-Cost Trial Basis

If Defendants were permitted to pursue their plan to distribute their infringing products to key opinion leaders on a no-cost trial basis, there would be a substantial risk Illumina would suffer irreparable harm. Defendants' marketing initiative for its imitative products would, in that event, cause Illumina to lose business opportunities, tarnish its reputation as the exclusive provider of its patented azido sequencing chemistry, and put downward pressure on its pricing, all of which are unquantifiable and classic irreparable harms. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930–31 (Fed. Cir. 2012) (affirming a finding of irreparable harm based on "damage to [patentee's] price, reputation, and business opportunities" even where there was "difficulty quantifying the effect on reputation and business" to the patentee during "the growth stage of a product"); *see also Douglas Dynamics, LLC v. Buyers Prods. Co.,* 717 F. 3d 1336, 1344–45 (Fed. Cir. 2013) (reversing denial of an injunction and finding clear error in lower court's irreparable harm analysis, which ignored that marketplace exclusivity itself "is an intangible asset that is part

of the company's reputation"); *see also* Van Oene Decl. ¶ 67-68 (explaining why these harms are unquantifiable).

"So long as there is a significant threat of harm, a preliminary injunction may issue regardless of the magnitude of the harm." *QBAS Co., Ltd. v. C Walters Intercoastal Corp.*, 2010 WL 7785955, at *11 (C.D. Cal. Dec. 16, 2010). As the Federal Circuit has explained, a "party seeking injunctive relief must make a 'clear showing' that it is at risk of irreparable harm, which entails 'a ***likelihood*** of substantial and immediate irreparable injury.'" *Apple, Inc. v. Samsung Elec. Co., Ltd.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) (citing *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008) ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction.") (emphasis in original). When a patentee has demonstrated a risk of irreparable harm such as lost market share or foregone business opportunities, the availability of some monetary damages does not negate this showing. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008) (rejecting accused infringer's argument that harm to patentee was reparable due to availability of damages).

Illumina's Chief Commercial Officer, Mr. Mark Van Oene, submits a supporting declaration in which he explains the substantial risk of harm posed by Defendants' plan to distribute its infringing products to key opinion leaders in the United States on a no-cost trial basis. *See* Van Oene Decl. ¶¶ 25-69.

1. Illumina Would Suffer Reputational Harm From Defendants' Planned Infringements

In the genetic sequencing field, suppliers routinely engage with key opinion leaders as a typical part of a commercial launch strategy. *See* Van Oene Decl. ¶¶ 26-28. Key opinion leaders are often associated with prestigious universities or research centers, and placing sequencers with them is important for a supplier's commercial reputation because they have substantial influence on the industry's perception of a brand and the purchasing decisions of other customers in the field. *Id.* ¶ 27, 48. The U.S. market is especially important for establishing and maintaining relationships with key opinion leaders because the U.S. includes a high concentration of key opinion leaders, including world renowned institutions with global reputations in sequencing expertise. *Id.*

Because key opinion leaders tend to be prestigious institutions that are highly visible in the marketplace, providing infringing BGI products to even a small number of key opinion leaders would likely cause substantial irreparable harm to Illumina's reputation, brand, and market position. *Id.* ¶ 51. Even a small number of key opinion leaders can influence many other key players in the marketplace, and the potential harm is especially severe because the Defendants could use infringement to usurp Illumina's customer relationships, goodwill, and brand recognition in a nascent, rapidly-growing market. *Id.* ¶¶ 25, 51-52. The Defendants' planned infringements would irreparably harm Illumina's commercial reputation in the field and its relationships with key opinion leaders, while allowing Defendants to seed the market with their infringing products and use key opinion leaders to influence others in the field (both in the U.S. and abroad) to use Defendants' sequencers, reagents, and services instead of Illumina's patented products and services. *Id.* ¶¶ 47, 50, 52.

2. Illumina Would Lose Sales And Business Opportunities From Defendants' Planned Infringements

Illumina directly competes against the Defendants for sales of sequencers, consumables, and services based on Illumina's patented technology. *Id.* ¶¶ 33-41, 47, 52, 57, 59. For example, MGI has marketed its DNBSEQ-G400 in direct competition with Illumina's sequencers. *Id.* ¶ 47 (Ex. T). The Defendants have been able to offer lower prices than Illumina by free-riding off of the enormous research and development investments that Illumina incurred in order to develop the innovations claimed by the '537 and '200 Patents. *Id.* ¶¶ 19, 23, 60, 67. Illumina has already lost sales to the Defendants in markets outside the U.S. due to their price undercutting. *Id.* ¶ 57.

In addition to the harm to Illumina' reputation and brand, allowing Defendants to proceed with their planned infringing activities would cause Illumina to lose sales and business opportunities with both key opinion leaders in the U.S. and other customers that they influence. *Id.* ¶¶ 52, 60. Key opinion leaders are an important revenue source for Illumina because they tend to be large customers that purchase instruments and substantial amounts of consumables and services for use in their academic work and research. *Id.* ¶¶ 28, 47, 59. Illumina also generates the majority of its revenues from customers in the U.S., which is the largest sequencing market in the world. *Id.* ¶28.

Allowing key opinion leaders to try the Defendants' infringing systems on a "no-cost trial basis" would unfairly encourage these opinion leaders and others to use the infringing products and associated services instead of purchasing Illumina's technology. *Id*. ¶52. The goal of such placements is to entice such opinion leaders and others to choose the Defendants' infringing products over Illumina's products based on cost, at a crucial time when the market is nascent and rapidly growing. *Id*. ¶¶ 25, 51-52.

The harm to Illumina's market share and losses in business opportunities would be irreparable and particularly difficult to quantify at least because the losses would involve prospective customer relationships in a nascent market. *Id*. ¶¶ 52, 68. Further, because sequencing customers tend to show significant loyalty to their initial supplier and are reluctant to change sequencing instruments once they become accustomed to them, it would be more difficult for Illumina to sell products to new or existing customers once Defendants have distributed infringing products to them, even if on a no-cost trial basis. *Id*. ¶¶ 29, 60-62.

3. Illumina Would Suffer Price Erosion From Defendants' Planned Infringements

Defendants' planned infringements would also likely cause price erosion. *Id*. ¶¶ 62-66. The Defendants have already caused Illumina to suffer price erosion in foreign markets such as China. *Id.* ¶¶ 63-64. Even if the Defendants' penetration into the U.S. market were limited to a small number of key opinion leaders "on a no-cost basis," Defendants' mere presence in the market would likely cause price erosion. *Id.* ¶¶ 51, 66. Current and prospective customers often use Defendants' presence and cut-rate pricing to negotiate and attempt to extract price concessions from Illumina. *Id.* ¶¶ 51, 66. If MGI supplies sequencers to key opinion leaders "on a no-cost trial basis," Illumina would likely have to offer substantial discounts or be faced with a loss of business and damage to its longstanding customer relationships. *Id*. ¶¶ 65, 66. And once one customer receives a discount, then other customers will expect the same. *Id.* ¶ 51.

Any discounting that Illumina is forced to undertake in response to Defendants' planned infringements would likely be irreversible. *Id.* ¶ 65. This harm would be irreparable, at least

because the impact on Illumina's customer relationships, customer goodwill, brand, and change in pricing structure cannot be easily quantified. *Id.* ¶ 62.

4. Illumina Would Suffer Irreparable Harm If Defendants' Planned Infringements Were Used To Promote A Different Sequencing Chemistry

If Defendants were to use the accused products to accustom key opinion leaders (and those they influence) with Defendants' products, including its sequencers, and help sell a different sequencing chemistry, that would be an infringing and commercial use that would cause irreparable harm to Illumina, including reputational harm, lost market share, and eroded pricing. *Id.* ¶ 53. Defendants should not be allowed to infringe Illumina's patents to build confidence in Defendants' imitative products, and then switch to a different sequencing chemistry. Nor should Defendants be allowed to use Illumina's proven, patented technology to seed the U.S. market by placing its instruments with key opinion leaders to develop relationships with them because it accelerates commercial entry and paves the way for Defendants to directly compete against Illumina. *Id.*

5. Defendants' Planned Infringements Are Not "Incidental"

Defendants' plan to provide its products on a "no-cost trial basis," or use them for comparative testing and to solicit feedback, does not negate the irreparable harm to Illumina. *Id.* ¶ 52. Defendants' planned infringing activities are anything but "incidental." *Id.* ¶¶ 47, 49. Placing instruments with key opinion leaders in the U.S. would seed the market with Defendants' products and lay the necessary groundwork for commercialization. *Id.* ¶ 49. Even if Defendants' instruments were initially placed on a "no-cost trial basis," this would give them a key entry point into the U.S. market to allow them to embed themselves with Illumina's current and prospective customers, while taking KOL time and mindshare away from Illumina's products, as Defendants perform installs, troubleshooting, training, and services for these customers once their instruments are placed. *Id.* ¶ 49.

Defendants' product give-away plan is not credibly for conducting research to develop new sequencers or reagents. *Id.* ¶ 54. It is the same commercial strategy that Defendants have used in other countries such as Germany to seed the market as part of their attempted commercial rollout

in those countries. *Id.* Defendants do not need to do R&D on the accused chemistry in the U.S. (in part) because it is based on Illumina's already-proven technology, which Defendants have been offering in foreign markets since at least 2016. *Id.* Nor do Defendants need to distribute the DNBSEQ-G400 sequencer to U.S. KOLs to receive feedback on it or conduct research into its development because it is a mature product that MGI launched back in October 2017. *Id.* Defendants similarly have no need to distribute their instruments to key opinion leaders in the U.S. in order to perform research and development on their allegedly "new chemistry" because they have already done this elsewhere and published the results. *Id.* There is also no reason why Defendants cannot perform research to develop new products in China, where they claim to already have a 35% market share, or in a jurisdiction where Illumina does not have patents covering the technology. *Id.*

Additionally, Defendants have no need to place instruments in the U.S. in order to conduct research and development, do comparative testing, or solicit feedback because this can be done through BGI's existing "test send out" service through which it contracts with companies and institutions to analyze samples remotely in its laboratories in China. *Id.* ¶ 55. Defendants also have the option to invite key opinion leaders to their laboratories in China to use Defendants' instruments there. *Id.* Such invitations are common practice in the industry. *Id.* If Defendants' planned infringements were truly "incidental" with no commercial purpose, then they would have taken a different course, rather than incurring the inevitable legal problems that would predictably result from blatant, willful infringement.

Similarly, Defendants' own use of their infringing sequencers and sequencing reagents in their San Jose facility to collaborate with key opinion leaders would be anything but incidental. It would create the same risk of harm to Illumina's business and reputation detailed above because key opinion leaders have immense influence in the market and are significant potential customers themselves. Id. ¶¶ 27, 48, 51. Consequently, Defendants should be enjoined from both distributing their infringing sequencers and sequencing reagents in the United States and using those products in the United States themselves to collaborate with others or promote them to third parties such as key opinion leaders.

C. The Balance Of Harms Favors A Preliminary Injunction

In deciding whether to grant a preliminary injunction, a court must consider the "harm that will occur to the moving party from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted." *Hybritech Inc. v. Abbott Labs.,* 849 F.2d 1446, 1457 (Fed. Cir. 1988). When considering such motions, courts favor the policy of preserving the status quo. *Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 994 (Fed. Cir. 1985) ("It is well settled that the purpose of an interlocutory injunction is to preserve the status quo.").

Defendants have no legitimate interest in disturbing the status quo by distributing their infringing products on a no-cost trial basis to key opinion leaders. The sequencers Defendants want to give to key opinion leaders have been on the market for years. They have already been developed and further improvements can be tested outside the United States if Defendants do not infringe in those jurisdictions. Defendants have more than a thousand installed sequencers outside the United States.

D. The Public Interest Is Best Served By A Preliminary Injunction

It is well-established that "[i]n this case absent any other relevant concerns, …the public is best served by enforcing patents that are likely valid and infringed." *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). Only "in rare instances" have courts "exercised their discretion to deny injunctive relief in order to protect the public interest." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995). This is not a case that presents such a rare instance. To the contrary, in this case especially—where the Patent Office has confirmed and the Federal Circuit has upheld the validity of the patent-in-suit through IPR proceedings—the public interest is best served by a preliminary injunction.

VI. CONCLUSION

For the foregoing reasons, the Court should preliminarily enjoin the Defendants from further infringement of the '537 Patent and '200 Patent.

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Respectfully submitted,

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